

### Remarks

Claims 62, 69, 76, and 116-134 remain in this application and are presented for the Examiner's review and consideration. Claim 62 has been amended, and claims 1-61, 63-68, 70-75, and 77-115 are canceled. Applicant has added new claims 116-134.

#### 35 U.S.C. §112 Rejections

Claims 62, 63, 67, 69, 70, 76, and 107-115 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

Claims 62, 63, 67, 69, 70, 76, and 107-115 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

With regard to claims 62, 69, and 76, Applicant has removed the objected-to language from these claims. It should be understood that the removal of this language is being made to expedite prosecution and is not an admission concerning the merits of this rejection. With regard to claims 63, 67, 70, and 107-115, Applicant has canceled these claims. It should be understood that the cancellation of these claims is being made to expedite prosecution and is not an admission concerning the merits of this rejection.

#### 35 U.S.C. §102 Rejection based on Mears

Claims 62, 63, 67, 70, 76, 108, 110, 112, and 114 were rejected under 35 U.S.C. §102(b) as being anticipated by Mears (U.S. Patent No. 4,553,272). Specifically, the Examiner states:

Mears anticipates the claim language where an implant of Mears is inserted into openings in adjacent bones. This device thus creates a space (interpreted to mean a distance) between the femur (2) and the hip bone (4); see Figures 1 and 2 as well as column 3, line 26 to column 5, line 53. One implant (6) of Mears serves as a spacer as claimed. The expansion step is met by the expansion of the cell culture inside the body; the claim language does not require a physical or structural expansion.

In response, Applicant respectfully requests this rejection be withdrawn.

Mears discloses a method wherein isolated daughter cells are introduced into a porous implant member and cultured therein. The implant member is secured to the patient so as to

permit continued cell growth resulting in reconstruction of the desired tissue. (col. 2, lines 16-21). In general, cultured cells replicate rapidly to produce a large number of cells within about ten to fifteen days. (col. 7, lines 34-36).

Applicant, on the other hand, discloses devices for stabilization surgery and their methods of use. These prosthetic devices may be made of an expandable material. (p. 31, lines 17-25). Expansion can take place in one of two ways. The device itself can be compressed and then expand when placed in the body. Alternatively, the device may be made of a material which expands when it comes in contact with water or other bodily fluid. (p. 30, line 23 to p. 31, line 3). In Figure 10B, the expandable material (330) is placed into tissue (334). Seen in Figure 10A, as the expandable material expands, the distance between the expandable material and the tissue decreases. The expandable material continues to expand outward into the tissue, and eventually, the implant is locked into the host site. (p. 32, lines 4-14). In Figures 11A and 11B, a prosthetic device having an expandable material is placed within bone. Similar to the expansion described above, the expandable device expands which decreases the distance between the implant and bone and ultimately expands into the bone to thereby lock the implant to the bone. (p. 33, lines 12-21).

Therefore, independent claim 62 has been amended to now recite a method of stabilizing tissue including positioning an implant in a patient's body and expanding the implant by absorbing liquid into the implant. Applicant contends that Mears does not teach or suggest the expansion of the cultured cells through the absorption of liquid. Rather, the daughter cells of Mears grow on a porous structure and then continue to grow once implanted into the body. Applicant contends that "growth" of cells is not expansion through the absorption of liquid.

In light of the foregoing, independent claim 62 is respectfully submitted to be patentable over Mears. As claim 76 depends from claim 62 and necessarily includes all the elements of its base claim, Applicant submits that this claim is patentable as well. Since new claims 116-124 depend from claim 62, either directly or through an intervening claim, and necessarily include all the elements of their base claim, Applicant submits that these claims are patentable over Mears at least for the above stated reasons.

35 U.S.C. §102 Rejection based on Kensey

Claims 62, 63, 67, 69, 70, 76, and 107 were rejected under 35 U.S.C. §102(b) as being anticipated by Kensey (U.S. Patent No. 4,890,612). Specifically, the Examiners states:

Kensey anticipates the claim language where the tissue as claimed is one side of the tissue puncture, and the at least one other object as claimed is the other side of the tissue. The implant as claimed is met by [the] combination of the plug (102) and the toggle (106); see the abstract, Figure 9 and column 6, line 24 to column 9, line 3.

In response, Applicant respectfully requests this rejection be withdrawn.

Kensey discloses a device and method for sealing a puncture or incision formed percutaneously in tissue separating two internal portions of the body of a living being, such as punctures or incisions in blood vessels, ducts or lumens, gall bladders, livers, hearts, etc. (col. 2, lines 38-42). The puncture closure is inserted within an artery by way of a tubular body. A pusher pushes the closure through the tube forcing the closure out the end of the tube and into the artery. Once the closure is outside the confines of the tubular body, it expands or enlarges to its disk-shaped configuration. After the tubular body is withdrawn from the patient's body, the filament attached to the closure is pulled to cause the closure to move toward the puncture, until its anchor portion is within the puncture. This action hemostatically seals the puncture. (col. 5, lines 37-58).

In another embodiment of Kensey's device, the plunger is operated as described above to expel the closure. Once the closure is expelled, the device is held in this position for a short period of time, e.g., 15 to 60 seconds, to allow the foam at the tip of the closure to swell. The action effectively tips the toggle. The insertion device is then removed and the closure's filament then retracted. This action pulls the closure's plug back through the puncture or incision in the artery wall. (col. 7, lines 1-25).

As noted previously, Applicant discloses devices for stabilization surgery and their methods of use. These prosthetic devices may be made of an expandable material. (p. 31, lines 17-25). Expansion can take place in one of two ways. The device itself can be compressed and then expand when placed in the body. Alternatively, the device may be made of a material which expands when it comes in contact with water or other bodily fluid. (p. 30, line 23 to p. 31, line 3). As seen in Figures 10A, 10B, 11A, and 11B, the expandable material expands while the

implant is at the implantation site.

Therefore, independent claim 62 has been amended to now recite a method of stabilizing tissue including positioning an implant in a patient's body at an implantation site and expanding the implant by absorbing liquid into the implant while the implant is at the implantation site. Applicant contends that Kensey does not teach or suggest the expansion of the puncture closure while the closure is at the implantation site. Rather, the closure of Kensey is expelled from a tubular body and into an artery. While in the artery, the closure absorbs fluid and expands. Then, the closure is pulled by the filament to position the closure at the implantation site.

In light of the foregoing, independent claim 62 is respectfully submitted to be patentable over Kensey. As claims 69 and 76 depend from claim 62 and necessarily include all the elements of their base claim, Applicant submits that these claims are patentable as well. Since new claims 116-124 depend from claim 62, either directly or through an intervening claim, and necessarily include all the elements of their base claim, Applicant submits that these claims are patentable over Kensey at least for the above stated reasons. Applicant has canceled claims 63, 67, 70, and 107. It should be understood that these claims are being canceled to expedite prosecution and therefore, is not an admission that the claims are not patentable over Kensey.

#### Co-Pending Applications

The Examiner requested a list of related co-pending applications and a copy of such co-pending claims. The following table lists the co-pending applications which claim priority to the same parent application. Copies of the claims of these applications are attached.

<b>Application No.</b>	<b>Date Filed</b>	<b>Attorney Docket</b>
10/033,515	Oct 19, 2001	780-A02-006-10
10/279,402	Oct 24, 2002	780-A02-006-13
10/279,451	Oct 24, 2002	780-A02-006-14
10/372,065	Feb 21, 2003	780-A02-006-15
10/371,265	Feb 21, 2003	780-A02-006-16
10/793,266	Mar 4, 2004	780-A04-006-17
10/793,265	Mar 4, 2004	780-A04-006-18
10/793,287	Mar 4, 2004	780-A04-006-19

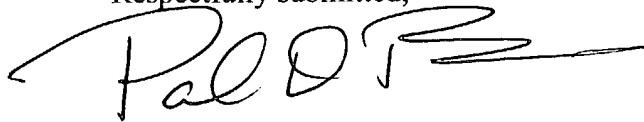
Applicant also notes that there is a series of pending applications based on U.S. Patent No. 5,269,785, entitled "Apparatus and Method for Tissue Removal." To err on the side of caution, Applicant is providing a list of these pending applications. Copies of the claims of these applications are attached as well.

Application No.	Date Filed	Attorney Docket
09/872,526	Jun 1, 2001	780-A02-014-7
10/003,996	Nov 15, 2001	780-A02-014-8
10/004,905	Dec 5, 2001	780-A02-014-10
10/104,250	Mar 22, 2002	780-A02-014-12
10/233,866	Sep 3, 2002	780-A02-014-13
10/233,865	Sep 3, 2002	780-A02-014-14

In light of the foregoing amendments and remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of \$385.00 is believed to be due for a Request for Continued Examination (small entity rate). Please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 780-A02-006-11).

Respectfully submitted,



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Enclosures